ISRCTN63192123 https://doi.org/10.1186/ISRCTN63192123

# A comparison of patient warming versus prophylactic antibiotics on the reduction of wound infection after breast surgery

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| **Submission date**<br>02/12/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>24/02/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>13/06/2017 | **Condition category**<br>Surgery | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
AP0978

## Study information

**Scientific Title**

Patient warming versus prophylactic antibiotics on the reduction of wound infection after breast surgery: a randomised controlled trial

### Study objectives
The principle objective is to compare the effect of local warming applied before and after surgery with prophylactic antibiotics on the rate of infection after breast surgery.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
South East Wales Research Ethics Committee

### Primary study design
Interventional

### Study design
Prospective randomised single-blinded controlled trial

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Breast surgery wound healing

### Interventions
Group A: patients receive treatment with a standardised prophylactic antibiotic
Group B: patients receive treatment of warming to the chest area using an exothermic warming pad
Group C: patients receive both prophylactic antibiotic treatment and patient warming

### Intervention Type
Procedure/Surgery

### Phase
Not Applicable

### Primary outcome(s)
The rate of wound infection during the 30-day follow-up period.

### Key secondary outcome(s)
1. Overall wound healing
2. Pain
3. Quality of life

### Completion date
31/12/2005

## Eligibility

### Key inclusion criteria
1. Female patients greater than or equal to 18 years
2. Having clean, non-implant, breast surgery

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Key exclusion criteria
1. Under 18 years
2. Pregnant
3. Current infection
4. Fine wire biopsy
5. Implant surgery
6. Diabetic

### Date of first enrolment
01/01/2004

### Date of final enrolment
31/12/2005

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**North Tees and Hartlepool NHS Trust**
Stockton-on-Tees
United Kingdom
TS19 8PE

## Sponsor information

**Organisation**
North Tees and Hartlepool NHS Foundation Trust (UK)

**ROR**
https://ror.org/04zzrht05

# Funder(s)

**Funder type**
Charity

**Funder Name**
Action Medical Research (UK)

**Alternative Name(s)**
action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/12/2011 | | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |